K140370

JUN 19 2014

510(k) Summary

Date Prepared: 19-Jun-2014

Besmed Health Business Corp.
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Official Contact: Winnie Chung
Regulatory Affairs Associate

Proprietary or Trade Name: Disposable Pressure Manometer

Common/Usual Name: Airway Pressure Monitor

Classification Name: 21CFR 868.2600
CAP – Airway Pressure Monitor
Class II

Predicate Devices: K003497 – Engineered Medical Systems – Pressure Monitor

Device Description:
The Besmed disposable pressure manometer is a means of providing visual indication of patient airway pressure during ventilation.

The device consists of:

1. A flexible nipple for attachment to a sampling / pressure port.
2. Clear housing with a printed pressure scale
3. A float with indicator
4. Spring

When positive pressure is present in the ventilation device, the manometer displays the pressure in the "circuit". The proposed design incorporates a calibrated spring, which has demonstrated reasonable accuracy over the expected clinical pressure range – 0-60 cm H_2O.

Besmed intends offer three (3) models / styles of their disposable pressure manometer.

They are identical in design, function and materials. The differences are:

- Pressure range
  - 0 – 60 cm H_2O
  - 0 – 40 cm H_2O
    - Rationale – some devices which may use a pressure manometer do not produce as high a pressure and the user often would like a lower limit pressure design
  - Note the accuracy and performances are identical
- Indicator strip
  - All models have the pressure range embossed on the housing
  - A color strip / indicator may also be included to indicate the pressure

It is a single patient, disposable, packaged non-sterile device.

Indications for Use:
To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits. For patients that the clinician desires to monitor or measure airway or circuit pressure, including neonates to adults. Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.

Substantial Equivalence Discussion:
Table 1 compares the key features of the proposed Besmed Disposable Pressure Manometer with the identified predicate and demonstrates that the device can be found to be substantially equivalent. In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K003497 – EMS pressure manometer.
Discussion – Each device is indicated for use to measure pressure in a circuit or airway.

Technology and construction –
The design, components, shape, size, etc., are equivalent to the predicate – K003497 – EMS pressure manometer.
Discussion – The design is simple housing with a float that sits on a spring that goes up or down based upon the pressure in the device. It has markings to indicate the pressure observed as well as a fixed leak to avoid over pressurization.

Environment of Use –
The environments of use are identical to predicate - K003497 – EMS pressure manometer.
Discussion – The environments of use are identical to the predicate - K003497 – EMS pressure manometer.

Patient Population –
The patient population is defined as patient where the clinician wants to measure or monitor circuit or airway pressure. The specific patient population is the same as the device to which it is attached which could be neonates to adults.
Discussion – The patient populations are equivalent to the predicate – K003497 – EMS pressure manometer.

Table 1 - Comparison to Predicates

Attribute	Predicate EMS – K003497 Pressure Manometer	Proposed Besmed DPM
Indications for Use	To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.	To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.
Patient population	Patient that the clinician desires to monitor or measure pressure, neonates to adults	Patient that the clinician desires to monitor or measure pressure.
Environments of use	Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.	Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.
Prescriptive	Yes	Yes
Single patient, disposable	Yes	Yes
Connects to a sampling port of any device, i.e. resuscitator, etc.	It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.	It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits.
Basic components	Housing Float Spring Pressure markings Fixed leak in the unit	Housing Float Spring Pressure markings Fixed leak in the unit
Pressure range	0 – 50 cm H_2O	0 – 60 cm H_2O
Models	Only one	Three 0-40, 0-60 with indicator stripe 0-60 with embossed pressure but no indicated stripe
Performance testing	Accuracy • $\pm$ 1 cm H_2O from 0-10 cm H_2O • $\pm$ 2 cm H_2O from 10-40 cm H_2O • $\pm$ 3 cm H_2O above 40 cm H_2O	Accuracy • $\pm$ 1 cm H_2O from 0-10 cm H_2O • $\pm$ 2 cm H_2O from 10-40 cm H_2O • $\pm$ 3 cm H_2O above 40 cm H_2O
		Age Testing – 5 years Pre and post- exposure Environmental Testing High / Low and Humidity conditions Drop test
Biocompatibility		• External Communication (Indirect contact) for all materials not in direct contact • Tissue communicating • Limited duration (<24 hours) • Identical materials to Besmed predicate

Non-Clinical Testing Summary –
We performed a number of tests including comparative pressure accuracy and the results demonstrated equivalent performance demonstrating the proposed device is equivalent to the – K003497 – EMS pressure manometer.

Testing included:

- Accuracy of pressure across the full pressure range to meet the pass / fail criteria
- Comparative accuracy testing showed no statistical difference in accuracy performance between the proposed device and the predicate, K003497 – EMS
- Age testing simulated to be equivalent to 5 years
- Environmental testing at high and low temperatures (MIL-STD-810E)
- Mechanical testing – Drop test

All testing demonstrated that the proposed device is substantially equivalent to the predicate device.

Substantial Equivalence Conclusion:

The proposed device has been found to be substantially equivalent to the predicate. Differences between the proposed device and the predicate do not raise new questions of safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2014

Besmed Health Business Corp.
c/o Paul Dryden
Consultant
No. 5, Lane 116, Wu-Kong 2nd Rd,
Wu-Ku District, New Taipei City, Taiwan

Re: K140370
Trade/Device Name: Disposable Pressure Manometer (RE-21466, RE-21464 and RE-21460)
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Manometer
Regulatory Class: Class II
Product Code: CAP
Dated: May 10, 2014
Received: May 13, 2014

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, MS
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140370

Device Name
Disposable Pressure Manometer

Indications for Use *(Describe)*

To provide visual indication of a patient's airway pressure during ventilation. It may be attached to the manometer port or proximal port on ventilation devices such as resuscitation bags, hyperinflation bags, CPAP mask, or CPAP circuits. For patients that the clinician desires to monitor or measure airway or circuit pressure, including neonates to adults. Home, Physician office, Hospital, Sub-acute Institutions, Emergency services or anywhere measurement of airway pressure is desired.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
2014.06.19
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